

## Food and Drug Administration, HHS

## § 516.21

years, except as otherwise provided by law or in this subpart.

### § 516.14 Submission of requests for designation.

All correspondence relating to a request for designation of a MUMS drug must be addressed to the Director of the Office of Minor Use and Minor Species Animal Drug Development. Submissions not including all elements specified in § 516.20 will be returned to the sponsor without review.

### § 516.16 Eligibility to request designation.

The person requesting designation must be the sponsor and the real party in interest of the development and the intended or actual production and sales of the drug or the permanent-resident U.S. agent for such a sponsor.

### § 516.20 Content and format of a request for MUMS-drug designation.

(a) A sponsor that submits a request for designation of a new animal drug intended for a minor use or minor species must submit each request in the form and containing the information required in paragraph (b) of this section. While a request for designation may involve multiple intended uses, each request for designation must constitute a separate submission. A sponsor may request MUMS-drug designation of a previously unapproved drug, or a new intended use or dosage form for an already conditionally approved or approved drug. Only one sponsor may receive MUMS-drug designation of the same drug, in the same dosage form, for the same intended use.

(b) A sponsor must submit two copies of a completed, dated, and signed request for designation that contains the following information:

(1) A request for designation of a new animal drug for a minor use or use in a minor species, which must be specific.

(2) The name and address of the sponsor; the name of the sponsor's primary contact person and/or permanent-resident U.S. agent including title, address, and telephone number; the established name (and proprietary name, if any) of the active pharmaceutical ingredient of the drug; and the name and

address of the source of the active pharmaceutical ingredient of the drug.

(3) A description of the proposed intended use for which the drug is being or will be investigated.

(4) A description of the drug and dosage form.

(5) A discussion of the scientific rationale for the intended use of the drug; specific reference, including date(s) of submission, to all data from nonclinical laboratory studies, clinical investigations, copies of pertinent unpublished and published papers, and other relevant data that are available to the sponsor, whether positive, negative, or inconclusive.

(6) A specific description of the product development plan for the drug, its dosage form, and its intended use.

(7) If the drug is intended for a minor use in a major species, documentation in accordance with § 516.21, with appended authoritative references, to demonstrate that such use is a minor use.

(8) A statement that the sponsor submitting the request is the real party in interest of the development and the intended or actual production and sales of the product.

(9) A statement that the sponsor acknowledges that, upon granting a request for MUMS designation, FDA will make information regarding the designation publicly available as specified in § 516.28.

[72 FR 41017, July 26, 2007, as amended at 75 FR 69588, Nov. 15, 2010; 77 FR 18685, Mar. 28, 2012]

### § 516.21 Documentation of minor use status.

So that FDA can determine whether a drug qualifies for MUMS-drug designation as a minor use in a major species under section 573 of the act, the sponsor shall include in its request to FDA for MUMS-drug designation under § 516.20 documentation demonstrating that the use is limited to a small number of animals (annualized). This documentation must include the following information:

(a) The estimated total number of animals to which the drug could potentially be administered on an annual basis for the treatment, control, or prevention of the disease or condition for

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which the drug is being developed, including animals administered the drug as part of herd or flock treatment, together with a list of the sources (including dates of information provided and literature citations) for the estimate.

(b) The estimated total number of animals referred to in paragraph (a) of this section may be further reduced to only a subset of the estimated total number of animals if administration of the drug is only medically justified for this subset. To establish this, requestors must demonstrate that administration of the drug to animals subject to the disease or condition for which the drug is being developed other than the subset is not medically justified. The sponsor must also include a list of the sources (including dates of information provided and literature citations) for the justification that administration of the drug to animals other than the targeted subset is medically inappropriate.

[72 FR 41017, July 26, 2007, as amended at 74 FR 43050, Aug. 25, 2009]

## § 516.22 Permanent-resident U.S. agent for foreign sponsor.

Every foreign sponsor that seeks MUMS-drug designation shall name a permanent resident of the United States as the sponsor's agent upon whom service of all processes, notices, orders, decisions, requirements, and other communications may be made on behalf of the sponsor. Notifications of changes in such agents or changes of address of agents should preferably be provided in advance, but not later than 60 days after the effective date of such changes. The permanent-resident U.S. agent may be an individual, firm, or domestic corporation and may represent any number of sponsors. The name and address of the permanent-resident U.S. agent shall be provided to the Director of the Office of Minor Use and Minor Species Animal Drug Development.

## § 516.23 Timing of requests for MUMS-drug designation.

A sponsor may request MUMS-drug designation at any time in the drug development process prior to the submission of an application for either condi-

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tional approval or approval of the MUMS drug for which designation is being requested.

## § 516.24 Granting MUMS-drug designation.

(a) FDA may grant the request for MUMS-drug designation if none of the reasons described in § 516.25 for refusal to grant such a request apply.

(b) When a request for MUMS-drug designation is granted, FDA will notify the sponsor in writing and will give public notice of the MUMS-drug designation in accordance with § 516.28.

## § 516.25 Refusal to grant MUMS-drug designation.

(a) FDA will refuse to grant a request for MUMS-drug designation if any of the following reasons apply:

(1) The drug is not intended for use in a minor species or FDA determines that there is insufficient evidence to demonstrate that the drug is intended for a minor use in a major species.

(2) The drug is the same drug in the same dosage form for the same intended use as one that already has a MUMS-drug designation but has not yet been conditionally approved or approved.

(3) The drug is the same drug in the same dosage form for the same intended use as one that is already conditionally approved or approved. A drug that FDA has found to be functionally superior is not considered the same drug as an already conditionally approved or approved drug even if it is otherwise the same drug in the same dosage form for the same intended use.

(4) The sponsor has failed to provide:

(i) A credible scientific rationale in support of the intended use,

(ii) Sufficient information about the product development plan for the drug, its dosage form, and its intended use to establish that adherence to the plan can lead to successful drug development in a timely manner, and

(iii) Any other information required under § 516.20.

(b) FDA may refuse to grant a request for MUMS-drug designation if the request for designation contains an untrue statement of material fact or omits material information.